DICYCLOMINE - dicyclomine hydrochloride tablet
STAT RX USA LLC

Revised 03/04
Rx Only

DESCRIPTION

Dicyclomine hydrochloride is an antispasmodic and anticholinergic (antimuscarinic) agent available in the following form:

Each tablet, for oral administration, contains 20 mg of dicyclomine hydrochloride. They also contain the following inactive ingredients: Anhydrous Lactose, FDandC Blue No. 1 Lake, Lactose Monohydrate, Magnesium Stearate, and Microcrystalline Cellulose.

Chemically, dicyclomine hydrochloride is [bicyclohexyl]-1-carboxylic acid, 2-(diethylamino) ethylester, hydrochloride with the structural formula:

Molecular Formula $C_{19}H_{35}NO_2 \cdot HCl$ M.W. 345.96 DICYCLOMINE 20MG

STRUCTURE IMAGE

Dicyclomine hydrochloride occurs as a fine, white, crystalline, practically odorless powder with a bitter taste. It is soluble in water, freely soluble in alcohol and chloroform, and very slightly soluble in ether

CLINICAL PHARMACOLOGY

Dicyclomine relieves smooth muscle spasm of the gastrointestinal tract. Animal studies indicate that this action is achieved via a dual mechanism: (1) a specific anticholinergic effect (antimuscarinic) at the acetylcholine-receptor sites with approximately 1/8 the milligram potency of atropine (in vitro, guinea pig ileum); and (2) a direct effect upon smooth muscle (musculotropic) as evidenced by dicyclomine's antagonism of bradykinin- and histamine-induced spasms of the isolated guinea pig ileum. Atropine did not affect responses to these two agonists. In vivo studies in cats and dogs showed dicyclomine to be equally potent against acetylcholine (ACh)- or barium chloride (BaCl2)-induced intestinal spasm while atropine was at least 200 times more potent against effects of ACh than BaCl2. Tests for mydriatic effects in mice showed that dicyclomine was approximately 1/500 as potent as atropine; antisialagogue tests in rabbits showed dicyclomine to be 1/300 as potent as atropine.

In man, dicyclomine is rapidly absorbed after oral administration, reaching peak values within 60-90 minutes. The principal route of elimination is via the urine (79.5% of the dose). Excretion also occurs in the feces, but to a lesser extent (8.4%). Mean half-life of plasma elimination in one study was determined to be approximately 1.8 hours when plasma concentrations were measured for 9 hours after a single dose. In subsequent studies, plasma concentrations were followed for up to 24 hours after a single dose, showing a secondary phase of elimination with a somewhat longer half-life. Mean volume of distribution for a 20 mg oral dose is approximately 3.65 L/kg suggesting extensive distribution in tissues.

In controlled clinical trials involving over 100 patients who received drug, 82% of patients treated for functional bowel/irritable bowel syndrome with dicyclomine hydrochloride at initial doses of 160 mg

daily (40 mg q.i.d.) demonstrated a favorable clinical response compared with 55% treated with placebo. (P less than .05). In these trials, most of the side effects were typically anticholinergic in nature (see table) and were reported by 61% of the patients.

Side Effect	Dicyclomine Hydrochloride (40 mg q.i.d.) %	Placebo %
Dry Mouth	33	5
Dizziness	29	2
Blurred Vision	27	2
Nausea	14	6
Light-Headedness	11	3
Drowsiness	9	1
Weakness	7	1
Nervousness	6	2

Nine percent (9%) of patients were discontinued from the drug because of one or more of these side effects (compared with 2% in the placebo group). In 41% of the patients with side effects, side effects disappeared or were tolerated at the 160 mg daily dose without reduction. A dose reduction from 160 mg daily to an average daily dose of 90 mg was required in 46% of the patients with side effects who then continued to experience a favorable clinical response; their side effects either disappeared or were tolerated. (See ADVERSE REACTIONS.)

INDICATIONS AND USAGE

For the treatment of functional bowel/irritable bowel syndrome.

CONTRAINDICATIONS

1. Obstructive uropathy
2. Obstructive disease of the gastrointestinal tract
3. Severe ulcerative colitis (See PRECAUTIONS)
4. Reflux esophagitis
5. Unstable cardiovascular status in acute hemorrhage
6. Glaucoma
7. Myasthenia gravis
8. Evidence of prior hypersensitivity to dicyclomine hydrochloride or other ingredients of these formulations
9. Infants less than 6 months of age (See WARNINGS and PRECAUTIONS: Information for Patients.)
10. Nursing Mothers (See WARNINGS and PRECAUTIONS: Information for Patients.)

WARNINGS

In the presence of a high environmental temperature, heat prostration can occur with drug use (fever and heat stroke due to decreased sweating). If symptoms occur, the drug should be discontinued and supportive measures instituted.

Diarrhea may be an early symptom of incomplete intestinal obstruction, especially in patients with ileostomy or colostomy. In this instance, treatment with this drug would be inappropriate and possibly harmful.

Dicyclomine hydrochloride may produce drowsiness or blurred vision. The patient should be warned not to engage in activities requiring mental alertness, such as operating a motor vehicle or other machinery or performing hazardous work while taking this drug.

Psychosis has been reported in sensitive individuals given anticholinergic drugs. CNS signs and symptoms include confusion, disorientation, short-term memory loss, hallucinations, dysarthria, ataxia, coma, euphoria, decreased anxiety, fatigue, insomnia, agitation and mannerisms, and inappropriate affect. These CNS signs and symptoms usually resolve within 12 to 24 hours after discontinuation of the drug.

DICYCLOMINE IS CONTRAINDICATED IN INFANTS LESS THAN 6 MONTHS OF AGE AND IN NURSING MOTHERS. (See CONTRAINDICATIONS and PRECAUTIONS: Nursing Mothers and Pediatric Use).

Safety and efficacy of dicyclomine hydrochloride in children have not been established.

HOW SUPPLIED

Dicyclomine Hydrochloride Tablets USP, 20 mg are supplied as blue, round, unscored tablets; embossed “WW 27” and are available in:

Bottles of 100 tablets.

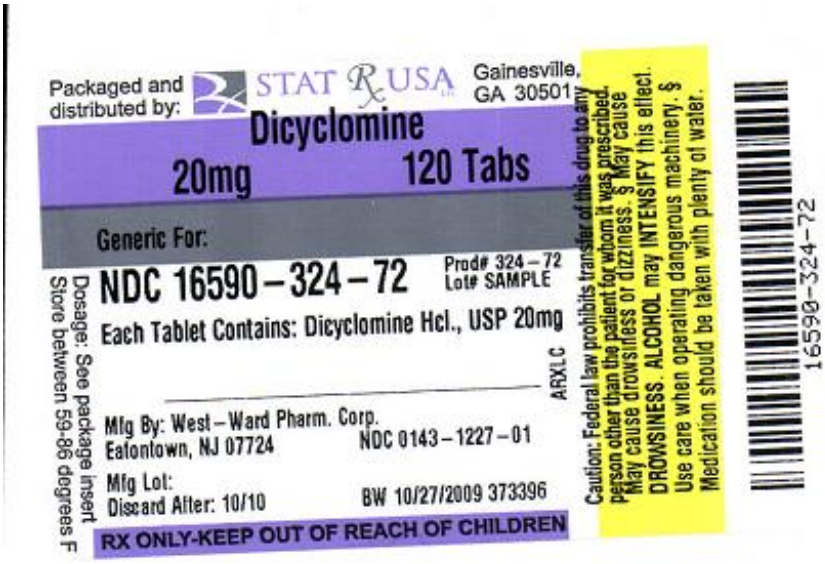
Bottles of 1000 tablets.

Unit Dose Boxes of 100 tablets.

To prevent fading, avoid exposure to direct sunlight. Store at 20°-25°C (68°-77°F) [See USP Controlled Room Temperature]. Protect from light and moisture.

Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure.

Manufactured By:
West-ward Pharmaceutical Corp.
Eatontown, NJ 07724
Revised March 200



DICYCLOMINE 20MG LABEL IMAGE

DICYCLOMINE

dicyclomine hydrochloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:16590-324(NDC:0143-1227)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DICYCLOMINE HYDROCHLORIDE (UNII: CQ903KQA31) (DICYCLOMINE - UNII:4KV4X8IF6V)	DICYCLOMINE HYDROCHLORIDE	20 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

Product Characteristics			
Color	blue	**Score**	no score
Shape	ROUND	**Size**	7mm
Flavor		**Imprint Code**	WW;27
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:16590-324-30	30 in 1 BOTTLE, PLASTIC		
2	NDC:16590-324-60	60 in 1 BOTTLE, PLASTIC		
3	NDC:16590-324-90	90 in 1 BOTTLE, PLASTIC		
4	NDC:16590-324-72	120 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040161	10/01/1996	

Labeler - STAT RX USA LLC (786036330)

Establishment

Name	Address	ID/FEI	Business Operations
STAT RX USA LLC		786036330	repack, relabel

Revised: 10/2009

STAT RX USA LLC